IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA
HARRISONBURG DIVISION

EMILY C. KELLINGTON, Plaintiff, v. BAYER HEALTHCARE PHARMACEUTICALS, INC., *et al.*, Defendants.	)	Civil Action No.: 5:14-cv-2 By: Elizabeth K. Dillon United States District Judge

MEMORANDUM OPINION

This is a personal injury case in which plaintiff, Emily Kellington, seeks to hold defendants, Bayer Healthcare Pharmaceuticals, Inc., Bayer Pharma AG, and Bayer OY (collectively defendants or Bayer), liable for personal injuries she contends she sustained as a result of using Mirena, a levonorgestrel-releasing intrauterine system manufactured by Bayer. Pending before the court and addressed herein is Bayer's motion to exclude (Dkt. No. 95), which has been fully briefed and was argued before the court. For the reasons set forth in this opinion, the motion will be granted in part and denied in part.

I. BACKGROUND

In its motion to exclude, Bayer seeks an order excluding certain expert opinions and reliance materials under Federal Rule of Civil Procedure 37(c)(1) on the grounds that they were not timely disclosed, and also asks for monetary sanctions. (Bayer's Mot. to Exclude, Dkt. No. 95.) While all parties agree that plaintiff timely submitted expert reports pursuant to Rule 26(a)(2), Bayer takes issue with certain opinions expressed and documents used at the depositions of four experts. Specifically, Bayer asserts that two of plaintiff's experts, Drs. Ross and Maggio, provided completely new opinions and new bases for existing opinions at their

depositions. A third expert, Dr. Fraunfelder, purportedly disclosed new reliance materials and testified that he had not finalized most of his opinions. And a fourth expert, Dr. Tang, revealed new reliance materials that served as the primary basis for one of her core opinions without ever producing those materials.

Plaintiff counters that her experts clarified existing opinions; that counsel merely defended and rehabilitated, or bolstered, her experts; and that no disclosure rule was violated.[1] Alternatively, plaintiff states that the experts supplemented their reports through their testimony, and so she filed supplemental "expert reports," following the depositions, which merely incorporate each expert's deposition testimony. (Dkt. No. 96-13.) Plaintiff further asserts that even if she failed to disclose in violation of a rule, the nondisclosure was justified or harmless. As part of this final contention, plaintiff contends that Bayer had the opportunity to examine plaintiff's experts at the depositions and could have asked to take supplemental depositions of the experts.[2]

II. DISCUSSION

A. Legal Standards Governing Expert Disclosures

Rule 26(a) requires an expert witness to submit a written report that contains "(i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; [and] (iii) any exhibits that will be used to summarize or support them . . . ." The report "should be a comprehensive document that, by itself, provides all the expert's opinions that will be offered at trial, along with the bases for those opinions." *Samsung Elecs. Co., v. Nvidia Corp.*, 314 F.R.D. 190, 198 (E.D. Va. 2016)

[1] Plaintiff also accuses defendants of providing new, extensive information on its reliance lists immediately prior to depositions of their experts. This matter, however, is not before the court because plaintiff has not filed any motion challenging Bayer's experts.

[2] At the hearing, plaintiff's counsel candidly admitted that he was unlikely to have granted such a request.

(citations omitted). The report then "form[s] the basis for informed deposition-taking." *Id*. There is also a duty to timely supplement expert reports if they are "incomplete or incorrect" "in some material respect" and "the additional or corrective information has not otherwise been made known to the other parties . . . ." Fed. R. Civ. P. 26(e)(1)(A). With regard to retained experts, the duty to supplement also includes information conveyed at the expert's deposition. Fed. R. Civ. P. 26(e)(2). The supplemental information is due no later than the deadline for pretrial disclosures under Rule 26(a)(3)—so thirty days before trial. *Id.*; Fed. R. Civ. P. 26(a)(3).

Courts have distinguished between supplementation and "gamesmanship." *Disney Enters., Inc. v. Kappos*, 923 F. Supp. 2d 788, 795 (E.D. Va. 2013). Supplementation is appropriate to "add or correct information," but a party may not use Rule 26(e) supplementation "whenever [it] wants to bolster or submit additional expert opinions" or it would "amount to unlimited expert opinion preparation." *Campbell v. United States*, 470 F. App'x 153, 157 (4th Cir. 2012). Put differently, the duty and ability to supplement "does not permit a party to make an end-run around the normal timetable for conducting discovery." *Colony Apartments v. Abacus Project Mgmt., Inc.*, 197 F. App'x 217, 231 (4th Cir. 2006); *see also East West, LLC v. Rahman*, 2012 WL 4105129, at *6 (E.D. Va. 2012) (quoting *Abacus*). Rather, supplementation is "only for the narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report." *Minebea Co. v. Papst*, 231 F.R.D. 3, 6 (D.D.C. 2005); *Disney Enters.*, 923 F. Supp. 2d at 795 (describing examples of "true supplementation" as "correcting inadvertent errors or omissions").

If there has been a failure to disclose timely all opinions or information, as required by Rule 26 or a pre-trial order, the court must determine whether the nondisclosure was substantially justified or harmless. If so, then no action is required by the court. Fed. R. Civ. P.

37(c). If not, then the party may not be allowed to use the witness or the information, or the court may impose "other appropriate sanctions" in addition to, or instead of, exclusion. *Id*. If the court finds a disclosure violation that is not substantially justified or harmless, it has "broad discretion to select an appropriate remedy in light of the totality of the circumstances." *S. States Rack & Fixture, Inc., v. Sherwin-Williams Co.*, 318 F.3d 592, 593 (4th Cir. 2003).

B. Challenged Opinions and Materials

With the law as stated above in mind, the court considers each of the experts whose opinions Bayer challenges. In this section, the court sets forth the eight items (allegedly new opinions and/or reliance materials) that Bayer seeks to exclude, the plaintiff's response regarding each of the eight items, and then provides the court's finding as to whether there was a nondisclosure. Within this structure, the court also provides a very brief summary of each expert's opinions. In a separate section that follows, the court considers whether—as to those materials or opinions that were not timely disclosed—the nondisclosure was harmless or substantially justified, and also determines any appropriate remedy.

Dr. David Ross - regulatory expert

By way of very brief summary, it appears from Dr. Ross's report that he concluded that there is a reasonable association between the use of Mirena and idiopathic intracranial hypertension (IIH),[3] and that there is reasonable evidence of a causative relationship. He stated that the reasonable evidence for an association was present at the time of Mirena's original approval, and the evidence supporting such a relationship has increased over time. He also

[3] The experts and parties use several different acronyms for the same basic condition or syndrome, although there are subtle differences between them. Bayer has generally used "idiopathic intracranial hypertension," or IIH, to refer to the syndrome. Some other drug labels or adverse event reports use either the terms pseudotumor cerebri (PTC), pseudotumor cerebri syndrome (PTCS), or the allegedly "obsolete" term, "benign intracranial hypertension." (*See* Ross Report 50–51, Dkt. No. 96-1; *see also* Pl.'s Resp. 3, Dkt. No. 104 (also referencing IH, BIH, SIH, and MIH).) For purposes of this opinion, the court will use IIH or PTC to refer to these conditions.

concluded that the FDA-approved labeling for Mirena has never contained a summary of the relevant, essential scientific information regarding the relationship between use of Mirena and IIH. (Ross Report 2, Dkt. No. 96-1.) His report stated that an adverse reaction must be listed on a label, even if it has not shown to be caused by the drug, if there is a "reasonable association, whether causal or not, between the reaction and the use of the drug." (Ross Report 30.)

Bayer challenges four opinions or aspects of Dr. Ross's testimony as being "new" and/or raised for the first time at his deposition:

1. *New Opinion on Other Drug Labels.* At his deposition, Dr. Ross testified as to the labels for a class of drugs called fluoroquinolones (antibacterial medicines) that warn of IIH, and analogized them to Mirena. (Ross Dep. 20–21, Dkt. No. 96-2 .) He pointed out that the labels for fluoroquinolones include information about reports of adverse events, even though there is not "absolutely proven, confirmed evidence of an association." (*Id.* at 74.) Dr. Ross admitted, though, that he had not reviewed the full body of data on that class of drugs to see how it compared to similar data of adverse effect reports for Mirena (*e.g.*, is there a stronger or weaker correlation). (*Id.* at 75–76.)

Plaintiff's Response: Plaintiff characterizes Dr. Ross's testimony about fluoroquinolones not as a new opinion, but as a "good example of the threshold of evidence needed by the FDA in order to require PTC warnings." (Pl.'s Resp. 14, Dkt. No. 104.) She points out that his report discussed this issue at length, citing to his report at 44–48. Plaintiff's counsel confirmed this characterization at the hearing.

Court's finding and ruling: The court agrees that Dr. Ross was simply providing an additional example of his opinion that warning labels for "adverse events" can include

information about adverse reports, even absent confirmed evidence of an association between the drug and the adverse reports. Thus, the court finds no violation of the disclosure rule.

2. *New Opinion on Clinical Trial Cases.* Bayer claims that Dr. Ross's reliance on a chart created by plaintiff's counsel, which purportedly showed three cases of "generic intracranial hypertension reported during clinical trials of levonorgestrel-containing IUDs" was a new opinion. (*See* Ross Dep. 386–89.) Dr. Ross admitted in his deposition that he was not previously aware of these three cases, and he offered opinions at his deposition concerning what the three cases meant. In particular, he said that those three incidences were "very concerning" and "strengthen[ed] the opinions in [his] report." (Ross Dep. 391.) Bayer then examined him about these three cases, at which point he testified that he may have missed them initially. (*Id.* at 442–43.)

Plaintiff's Response: Plaintiff admits that Dr. Ross did not recall reviewing information on these three cases prior to his deposition, and she also does not dispute that the three cases were not discussed in his report. While the data containing the three cases was disclosed as being among the original materials considered by Dr. Ross (Pl.'s Resp. 15), he testified he was not aware of the cases, so he could not have considered them in forming his opinions.[4]

Court's finding and ruling: The court finds that these cases were a new basis for Dr. Ross's opinion and were not properly disclosed.

[4] The three cases were referenced in three rows of data from an Excel spreadsheet produced by Bayer having 12,000 data points.

3. *New Opinion on Rechallenge Case*.[5] Bayer next argues that the questions from plaintiff's counsel and Ross's testimony regarding a specific rechallenge case involving Mirena should be excluded. Dr. Ross testified generally about rechallenges under questioning from Bayer's counsel. (Ross Dep. 233–37.) Then, he answered plaintiff's counsel's questions about the specific rechallenge case. (*Id.* at 392–400.) Defense counsel later questioned him about it, as well. (*Id.* at 460–63.)

Plaintiff's Response: Much like the first opinion (concerning the fluoroquinolones), plaintiff argues that this is simply another example that supports Dr. Ross's general opinion about the seriousness of a rechallenge event. (Pl.'s Resp. 17.) Also, like the three clinical cases discussed previously, the data about the rechallenge case was included in the spreadsheet listed as part of the materials Dr. Ross had reviewed. (*Id.*)

Court's finding and ruling: This is different than the fluoroquinolones issue. Here, Dr. Ross relied on data specifically concerning Mirena. And while that new data appears to support his general opinion that Mirena's label should warn of the risks of IIH and that there is an association, and even a causal relationship, between Mirena and IIH, this specific rechallenge case was certainly not discussed in his report, and bears on a critical issue in the case. Thus, it cannot be characterized as an example of the general statements in his report about rechallenge cases. The report simply said that "even a single well-documented case report can be viewed as a [safety] signal if the report describes a positive rechallenge or if the event is extremely rare in the absence of drug use." (Ross Report 37, 75 (quoting *The 2005 Guidance on*

[5] A "rechallenge" case is one in which a patient's symptoms stop upon stopping use of a particular drug, and then the symptoms restart when the drug is restarted. Dr. Ross said that generally such events are afforded particularly heavy weight in determining an association or causation between a drug and an illness. (Ross Report 37.)

Pharmacovigilance Practices and Pharmacoepidemiologic Assessment).) It did not identify any rechallenge case involving Mirena in support of that proposition. Accordingly, this is a completely new basis for his opinions and should have been disclosed in his report.

4. *New Disproportionality Analysis*. Bayer's last complaint as to Dr. Ross is that he "relied on the results of a new disproportionality analysis—the centerpiece of his opinions—that Plaintiff's counsel showed him for the first time during his deposition." (Bayer's Mem. 16, Dkt. No. 96.) Bayer calls this the "most egregious new material." (*Id*. at 5.) In his report, Dr. Ross discussed his disproportionality analysis at pages 68 and 69. (Ross Report 68–69.)

Plaintiff's Response: Plaintiff argues that her counsel was simply rehabilitating Dr. Ross after the "ordeal" of his questioning by Bayer's counsel. She contends that the analysis she presented during the deposition was offered to show that Dr. Ross's original results were reproducible, depending on the search terms used for a search. She presented this information after defendant's counsel had repeatedly tried to undermine the analysis performed by Dr. Ross.

Court's finding and ruling: Based on the totality of this testimony, it is undisputed that this specific search was not disclosed, but the court concludes that it is not a new opinion or a new basis for his opinion, because he never offered a conclusive opinion as to the new search. It appears that counsel ran the search the night before the deposition when trying to reproduce Dr. Ross's results, after they were challenged in the report of one of defendant's experts, Dr. Feigal. (Ross Dep. 27–29.) Then, after Dr. Ross was questioned about it, plaintiff's counsel tried to show him the report she had made to get him to explain any error in his report. This appears to be an attempt at classic "correction" to a report, albeit one made during the deposition, and by

counsel who is offering the expert. So, it may have been a proper ground for supplementation, had proper supplementation ever occurred.

Ultimately, however, Dr. Ross was not sure whether his initial analysis was correct or not, or exactly what search terms he had used or had not used. He repeatedly said he believed that plaintiff's counsel had identified any error in his report, but he would need to re-run the analysis and the search to confirm that. At the conclusion of his deposition, he did not know which analysis was right, and the defendant did not have the benefit of knowing what the bases for his opinion were. So, as it stands now, Dr. Ross has not actually offered any opinion based on the second analysis prepared by counsel, and it is not new reliance material. Thus, no disclosure violation occurred. The initial analysis was disclosed and may later present a *Daubert* issue, but that is not before the court now.

Dr. Rick Fraunfelder - ophthalmologist

Dr. Fraunfelder's report included five opinions, which he offered based on his experience and expertise as a medical doctor and as an expert in drug safety monitoring. First, he claimed that there are a number of adverse reports of "PTC and/or papilledema" associated with the use of levonorgestrel, or LNG. Second, he claimed that the number of reports suggests a relationship between LNG-containing hormonal contraceptives, such as Mirena, and PTC and/or papilledema. Third, he stated that epidemiological evidence suggests a likelihood that Mirena is associated with the development of PTC and/or papilledema, making it more likely than not that Mirena causes or contributes to the development of these conditions. His fourth and fifth opinions concerned labeling, although those opinions are not directly challenged here. (Fraunfelder Report 1, Dkt. No. 96-4.)

5. *Reliance on Three New Analyses.* Bayer complains that Dr. Fraunfelder brought to his deposition an entirely new VigiBase search (a 232-page document) performed the prior evening by his assistant, as well as two additional VigiBase searches not disclosed in his expert report. He clearly admitted as much. (Fraunfelder Dep. 150, Dkt. No. 96-3 (agreeing with the statement that "the output of those [three] searches [is] not contained in [his] report.").) Bayer also points out that Dr. Fraunfelder admitted he had not thoroughly reviewed the most recent search, but nonetheless stated that it was a "supplement to the spontaneous report aspect of [his] basis of [his] opinion." (*Id.* at 49.)

Plaintiff's Response: Plaintiff responds that Dr. Fraunfelder has a duty to supplement his report and argues that these additional reports were simply proper supplementation. (Pl.'s Resp. 9–10.) She also contends that his expert report notes that there are adverse event case reports of PTC associated with use of LNG. She claims that his testimony that he may continue to draw on new reports "is not inconsistent with his report or with accepted scientific principles." (*Id.* at 10.)

Court's finding and ruling: At the hearing, plaintiff's counsel agreed that the 232-page VigiBase search report can be excluded as a basis for Dr. Fraunfelder's opinion. By agreement, then, the court excludes that search report. The other two VigiBase search reports[6] were produced in advance of the deposition, but Dr. Fraunfelder, while relying on them to supplement his opinion, had not thoroughly reviewed the searches and could not be questioned adequately on them for that reason. An expert cannot merely state that he is relying upon information that he has not reviewed adequately and avoid being questioned about the same. Either these two

[6] It appears that the VigiBase is updated quarterly, so an expert could rely upon new information that was not previously available to supplement a report. It is not clear, however, that this is what Dr. Fraunfelder was doing.

reports are not reliance materials at all and will not be considered as such, or the materials were not timely disclosed.

6. *Refusal to Commit to Final Opinions and Analyses*. Bayer also notes that Dr. Fraunfelder repeatedly "reserved the right" to later supplement his opinions or to add to them, which Bayer states is simply illustrative of the problem with all four of these experts. Bayer complains that they have not "finalized" their opinions, making it impossible for Bayer to finish deposing them, and thus prejudicing Bayer.

Plaintiff's Response: Plaintiff's response is essentially the same as her response to Issue 5 above: it is appropriate for an expert to supplement and update his report with new information.

Court's finding and ruling: Dr. Fraunfelder has missed the point of his deposition and fails to understand that his testimony was supposed to be finalized before his deposition, so it could be tested or examined there by Bayer's counsel. There is certainly no provision that allows unlimited "supplementation" in the sense of adding opinions or bases for them or support for them up until he testifies at trial. That would defeat the entire purpose of depositions and would create an endless cycle of supplementation without any consequences. As to any issue on which Dr. Fraunfelder "reserved" his right to supplement, then, the court will not allow this supposed reservation to be used to introduce at trial previously undisclosed opinions or bases for them. That being said, there are simply no new opinions or reliance materials challenged in Item 6, so there is nothing to exclude as untimely disclosed, and the court makes no ruling with regard to Item 6.

Dr. John Maggio - pharmacologist

Dr. Maggio is not a medical doctor, but is a research scientist. Dr. Maggio's report focused on the background of hormonal contraception, and included a discussion of the chemistry behind it. It also explains in detail how LNG is believed to work. (*See* Maggio Report 19, Dkt. No. 96-5.) His opinions are listed on pages 1–2 of his report (*id.* at 1–2), and the court will not repeat them completely here. But he concluded that studies and case reports strongly suggest a significant association between LNG and IIH and, in particular, between Mirena and IIH. He also opined that a "significant fraction of Mirena users show higher systemic LNG exposure than the average user of certain former devices (like Norplant), but the Mirena label does not contain a warning about IIH." He stated it is "more likely than not that the high systemic levels of [LNG] in some users of the Mirena [IUD] can cause or substantially contribute to the development of [IIH]. The Mirena label should bear a warning for [IIH]." (*Id.* at 2.)

7. *New Opinions on Thirteen Documents.* According to Bayer, during Dr. Maggio's deposition, he provided new opinions on thirteen documents that plaintiff's counsel had left the deposition to gather. (Maggio Dep. 348, Dkt. No. 96-6.)[7] The documents included clinical study reports, internal copy documents, and published articles containing data on serum blood concentrations for Mirena. More than half of these documents were not on Dr. Maggio's reliance list, and thus he had not considered these documents prior to submitting his report. Bayer

[7] These were exhibits 40–49 and 51–53 to his deposition, although neither party has given the court copies of them.

also explains, in a footnote, that Dr. Maggio admitted at his deposition that the causation opinion was based on a single pharmacokinetic study. (*Id.* at 157.)[8]

Plaintiff's Response: Plaintiff claims—falsely, according to Bayer—that "no new material was proffered at the deposition." (Pl.'s Resp. 19.) She explains that the documents (which were all documents Bayer produced) were tendered in order to demonstrate the correctness of Dr. Maggio's alleged "assumption," which was that the patients in the one study he relied upon (and assumed was reasonable because it was published by Bayer and for other reasons), were representative of Mirena users. She further claims that the additional documents merely showed that he was correct and that the serum levels of the patients in the one study were representative, or at least consistent with, the serum levels in other studies.

Court's finding and ruling: A review of Dr. Maggio's deposition transcript did not reveal to the court thirteen new opinions based upon thirteen documents, and the thirteen documents were not provided to the court. It appears, however, that some of the thirteen documents may not have been identified to Bayer in advance of the deposition as reliance materials. (Maggio Dep. at 349 (defense counsel objecting on this ground).) It appears, from at least some of the testimony, that Dr. Maggio may have been asked to merely state what was in a document shown to him. It is hard for the court to determine whether this is the case, and the court will not finely sift through the testimony, without even the benefit of the documents, to try to determine what might be a new opinion, what might be new reliance materials, and what might be merely a document shown to Dr. Maggio for some comment. Bayer, in bringing this motion, must show that there has been a violation of a disclosure rule, and it has not done so with regard to Dr. Maggio.

[8] Bayer challenges the reliability of his opinions and the data on which they are based, but asserts it is not bringing a *Daubert* motion at this time. Thus, the court does not consider these arguments, which are more appropriately addressed in a *Daubert* motion.

Dr. Rosa Tang - neuro-ophthalmologist

Dr. Tang will be offered to testify generally about IIH (or its other used terms), how it is diagnosed and treated, and its impacts on a patient's life. She will also testify about "other causes of intracranial hypertension" and known associations. Her report also discussed labeling to some degree, although she initially testified at her deposition that she is not an expert in labeling or regulatory matters and later clarified that, although she is not a scientific "expert" on the labeling issue, she could offer helpful information to a jury. Her report offered two "conclusions to a reasonable degree of medical certainty and based on her background and experience." (Tang Report 9, Dkt. No. 96-8.) First, she concluded that Mirena is likely associated with (but not necessarily causally related to) the development of intracranial hypertension. (*Id*.) She also says Mirena's "labeling may be inadequate . . . to alert physicians" about the association. (*Id*.) With regard specifically to Ms. Kellington, she opines that Kellington developed "Mirena Induced Intracranial Hypertension." (*Id.* at 10.)

8. *New Database of reliance materials.* Bayer contends that Dr. Tang testified that her opinion that Mirena is associated with IIH comes "mainly" from her experience in the 1990s with patients using Norplant. It claims that she "formed her core Mirena opinion based on her decades-old Norplant research." (Bayer's Mem. 13.) It relies on the following pages from her May 10, 2016 deposition: 416–417, 234–235, 284–86. Relatedly, Bayer complains that plaintiff has "promised" to provide those documents, but is now refusing to do so unless Bayer pays for Dr. Tang's time in searching for them.

Plaintiff's Response: Plaintiff contends that Bayer is taking Dr. Tang's statements out of context and that she was not in fact relying on those studies for her association opinion. Instead,

Dr. Tang testified that her history with the drug Norplant was in relation to her experience in treating patients with IIH, and that her earlier study did not serve as the basis for opinions, nor did she rely on it. Based on the emails exchanged by counsel on the subject, it appears plaintiff's position is that Dr. Tang could not have relied on documents she has not looked at in more than 20 years, that she was just relying on her experience, and that her "experience" and whatever the documents may be are two different things. (*See, e.g.*, Bayer's Mem. Ex. 12, at 3, 5, Dkt. No. 96-12.) As to the issue of producing the Norplant files or research, plaintiff further argues that she should not have to pay for Dr. Tang to find studies that she is not relying on to form her opinions.

Court's finding and ruling: It is patently clear that Dr. Tang is, in fact, relying on her experience with Norplant and treating women who used Norplant and developed IIH. When she was asked what information she was relying on for her opinion that Mirena is likely associated with the development of intracranial hypertension, she responded that she was "[m]ostly relying on what levonorgestrel can do from when I had my experience with Norplant . . . ." (Tang May 10, 2016 Dep. 234–35, Dkt. No. 96-7.) She was then asked: "So you're relying on your clinical experience from treating patients with Norplant?" She answered, "Yes." (*Id.*) She then also referred to several other bases for her opinion, including textbooks related to Norplant, and the Rai report. (*Id.* at 236–37.) Also, her report itself identified her experience with Norplant and IIH (which she describes as "reviewing multiple cases of young women who developed a syndrome of intracranial hypertension while on Norplant.") (Tang Report 5.) And she claims that these cases were "Norplant induced." (*Id.*)

She testified that she thought she had documents in storage that related to a poster that she presented at a conference. The poster concerned the association of Norplant and intracranial

hypertension. Although the poster never developed into a controlled study, due to funding problems, she nonetheless had gathered information about 100 patients, who she recruited by reaching out to ophthalmologists in Texas to see if they had any Norplant patients. (Tang May 10, 2016 Dep. 285.) She then examined "most, if not all, of these patients" prior to presenting her poster at the conference. (*Id.*) The research related to these 100 patients, which she did not consult in writing her expert report, is what she thought she had in storage.

Even if Dr. Tang meant she was relying on her "experience with Norplant" in a more general sense (that she evaluated women who received levonorgestrel and developed IIH), Bayer is entitled to the information that she relied on to reach that conclusion, *i.e.*, her treatment notes reflecting, for example, the weight of the women, their actual histories and use of the drugs, etc. Bayer is entitled to probe the bases for her opinion and the strength of the Norplant-IIH connection vis-à-vis the Mirena-IIH connection. It is difficult to do so without those notes.

C. Remedy

The court finds disclosure violations with regard to Drs. Ross (Items 2 and 3) and Fraunfelder (Item 5) and an inadvertent nondisclosure with regard to Dr. Tang. Bayer has failed to show a violation of the disclosure rule with regard to Dr. Maggio, so no remedy is necessary with regard to his report or deposition testimony.

Because the court finds nondisclosure violations, the court turns to whether the nondisclosures were harmless or substantially justified. The party failing to disclose bears the burden of proof as to justification and harmlessness. *Quesenberry v. Volvo Grp. N. Am., Inc.*, 267 F.R.D. 475, 478 (W.D. Va. 2010) (citing *S. States Rack & Fixture*, 318 F.3d at 596). To determine whether the nondisclosure was harmless, the court looks to "surprise to the opposing party, ability to cure that surprise, disruption of the trial, and importance of the evidence." *S.*

States Rack & Fixture, Inc., 318 F.3d at 597. To determine whether the nondisclosure was substantially justified, the court looks to the "explanation for the nondisclosure." *Id*.

The court easily finds that the nondisclosures were not substantially justified. Indeed, plaintiff provided no explanation or justification for any nondisclosures, instead arguing only that there were no disclosure violations. There is certainly no justification evident from the record, either.

As to whether the nondisclosures were harmless, plaintiff argues that even if there was a disclosure violation, there was no surprise, and that Bayer had the ability to cure any surprise because it was able to examine all four experts at their depositions. She also points out that the depositions were completed six weeks before the expert discovery deadline, and Bayer could have asked for supplemental depositions, but did not. As recently stated in *Samsung*, however, "notice in deposition testimony does not render a failure to disclose in the expert report unsurprising or curable, even when that deposition testimony completely covers the material that should have been disclosed." *Samsung*, 314 F.R.D. at 198 (citations omitted). This is because "disclosure in the right form (complete) and at the right time (with the expert report, before the expert's deposition) is critical to an opposing party's ability to engage in meaningful expert discovery (critical analysis of the expert's report, and taking of a targeted deposition)." *Id*.

That reasoning is on display here. Bayer was surprised at the depositions of Dr. Ross and Dr. Fraunfelder by new opinions and/or reliance materials. Bayer's ability to examine Dr. Ross and Dr. Fraunfelder about the new opinions/materials at their respective depositions was not an adequate cure for the surprise. Especially when expert witnesses are deposed, the opposing party often plans carefully for examination in advance of the deposition, relying upon the expert's report and consultation with that party's own experts. An immediate examination, without

consultation and careful planning and review, regarding new opinions or materials, is not an adequate or fair substitute. Plaintiff's suggested cure—to permit supplemental depositions—is disingenuous given her admission that such a request was not likely to have been voluntarily granted.

In any event, to allow additional depositions for new disclosures would be disruptive to the trial. The trial is scheduled to begin November 29, 2016, and is scheduled for four weeks, making it difficult to reschedule easily or within a few months. Further, the scheduling order has important deadlines designed to ensure that the case will be ready for trial as scheduled, and those deadlines are upon the parties now.

Plaintiff provided little, if any, information about the importance of the evidence, and the court finds that plaintiff has not demonstrated the importance of the new opinions and materials. For all of these reasons, the new opinions and reliance materials are not substantially justified or harmless and will be excluded.

Dr. Tang's underlying Norplant research and records were supplemental information that was inadvertently omitted as reliance materials, but was referenced in her report. The parties represent that they have been paying for their own experts' time and expenses; thus, the court orders that Dr. Tang search for the documents in storage at plaintiff's cost and either produce what she finds or report the search efforts that resulted in the inability to locate the documents in storage no later than September 14, 2016, or another date upon agreement by the parties. Plaintiff is then to make Dr. Tang available for a supplemental deposition if requested by Bayer no later than September 28, 2016, or another date upon agreement by the parties. Bayer will bear its own costs of the supplemental deposition. If Dr. Tang is re-deposed, the court will allow a separate *Daubert* motion to be filed regarding Dr. Tang no later than October 5, 2016.

The court finds the above remedies to be sufficient to remedy the violations and will not grant any additional sanctions requested by Bayer.

III. CONCLUSION

For the reasons set forth above, Bayer's motion to exclude will be granted in part and denied in part. A separate order will be entered.

Entered: August 30, 2016

/s/ Elizabeth K. Dillon
United States District Judge